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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,955	02/28/2001	Reld W. Von Borstel	1331-334	3848

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EXAMINER	
YOUNG, JOSEPHINE	14

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,955	VON BORSTEL, RELD W.	
	Examiner	Art Unit	
	Josephine Young	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *48-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's amendment canceling previous claims 1-47 and adding new claims 48-69 in Paper No. 13, mailed December 30, 2002, in response to the Office Action mailed October 1, 2002, is acknowledged.

Newly presented claims 48-69 are now subject to a restriction requirement under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 48-59 and 62-68, drawn to methods for treating or preventing a disease related to mitochondrial dysfunction using a pyrimidine nucleoside. such as cytidine or uridine, or its acyl derivative.

Group II, claim(s) 48-59, drawn to methods for treating or preventing a disease related to mitochondrial dysfunction using a phosphocholine derivative of a pyrimidine nucleotide.

Group III, claim(s) 48-59, drawn to methods for treating or preventing a disease related to mitochondrial dysfunction using a nucleobase, such as orotic acid, or an alcohol ester of a nucleobase.

Group IV, claim(s) 48-59, drawn to methods for treating or preventing a disease related to mitochondrial dysfunction using a pyrimidine nucleotide precursor, other than a pyrimidine nucleoside, an acyl derivative of a pyrimidine nucleoside, a phosphocholine derivative of a pyrimidine nucleotide, a nucleobase and an alcohol ester of a nucleobase.

Group V, claim(s) 60-61 and 69, drawn to methods for reducing side effects of cytotoxic cancer chemotherapy agents using a pyrimidine nucleoside, such as cytidine or uridine, or its acyl derivative.

Group VI, claim(s) 60-61, drawn to methods for reducing side effects of cytotoxic cancer chemotherapy agents using a phosphocholine derivative of a pyrimidine nucleotide.

Group VII, claim(s) 60-61, drawn to methods for reducing side effects of cytotoxic cancer chemotherapy agents using a nucleobase, such as orotic acid, or an alcohol ester of a nucleobase.

Group VIII, claim(s) 60-61, drawn to methods for reducing side effects of cytotoxic cancer chemotherapy agents using a pyrimidine nucleotide precursor, other than a pyrimidine nucleoside, an acyl derivative of a pyrimidine nucleoside, a phosphocholine derivative of a pyrimidine nucleotide, a nucleobase and an alcohol ester of a nucleobase.

Claims 48-59 link Groups I-IV and will be examined together with the Group that is elected as it pertains to the elected invention. Claims 60-61 link Groups V-VIII and will be examined together with the Group that is elected as it pertains to the elected invention.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature linking claims 48-69 appears to be that they all relate to methods for using a pyrimidine nucleotide precursor in diseases/consequences/side effects related to mitochondrial dysfunction.

However, the article PAGE et al., Proceedings of the National Academy of Science USA, **October 1997**, *94* (21), 11601-11606 (U) teaches that when patients with developmental delay were treated with orally administered uridine, they had fewer seizures, decreased ataxia, improved speech and behavior, and improved performance on standardized tests of cognitive function. See page 11604, right column, first and second paragraphs. Therefore, by October of 1997, methods to treat autism and/or pervasive developmental disorder, a pathophysiological

consequence of mitochondrial dysfunction of the present invention, using uridine, a pyrimidine nucleotide precursor of the present invention, were known in the art.

Thus, the technical feature linking the invention of Groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be methods for treating or preventing a disease related to mitochondrial dysfunction using a pyrimidine nucleoside, such as cytidine or uridine, or its acyl derivative.

The special technical feature of Group II is considered to be methods for treating or preventing a disease related to mitochondrial dysfunction using a phosphocholine derivative of a pyrimidine nucleotide.

The special technical feature of Group III is considered to be methods for treating or preventing a disease related to mitochondrial dysfunction using a nucleobase, such as orotic acid, or an alcohol ester of a nucleobase.

The special technical feature of Group IV is considered to be methods for treating or preventing a disease related to mitochondrial dysfunction using a pyrimidine nucleotide precursor, other than a pyrimidine nucleoside, an acyl derivative of a pyrimidine nucleoside, a phosphocholine derivative of a pyrimidine nucleotide, a nucleobase and an alcohol ester of a nucleobase.

The special technical feature of Group V is considered to be methods for reducing side effects of cytotoxic cancer chemotherapy agents using a pyrimidine nucleoside, such as cytidine or uridine, or its acyl derivative.

The special technical feature of Group VI is considered to be methods for reducing side effects of cytotoxic cancer chemotherapy agents using a phosphocholine derivative of a pyrimidine nucleotide.

The special technical feature of Group VII is considered to be methods for reducing side effects of cytotoxic cancer chemotherapy agents using a nucleobase, such as orotic acid, or an alcohol ester of a nucleobase.

The special technical feature of Group VIII is considered to be methods for reducing side effects of cytotoxic cancer chemotherapy agents using a pyrimidine nucleotide precursor, other than a pyrimidine nucleoside, an acyl derivative of a pyrimidine nucleoside, a phosphocholine derivative of a pyrimidine nucleotide, a nucleobase and an alcohol ester of a nucleobase.

Accordingly, Groups I-VIII are not so linked by the same or corresponding special technical feature as to form a single general inventive concept.

Further, searching all of the inventions constitutes a burdensome search, as a thorough search comprises a search of foreign patents and non-patent literature, as well as the appropriate U.S. patent classifications. A reference for one group could not reasonably be expected to be a reference for another. To search the eight independent and distinct inventions, set forth supra, would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
March 19, 2003

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600